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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,670	02/15/2001	Yaping Zhu	540541-2029	2237

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,670

Applicant(s)

ZHU ET AL.

Examiner

Sandra Wegert

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 04 April 2002 (Paper No. 5) has been entered. Claims 1 and 8-14 were amended. Applicant elected the medicament *insulin* for prosecution in Paper 7 (12 October 2002) with traverse. The traversal is on the grounds that the disclosed invention is a polymeric construct with a medicament trapped within, and that it would not constitute an undue burden to examine all the medicaments recited. However, *insulin* and the other recited medicaments were properly restricted as distinct products having different chemical properties and having different properties as related to the carrier compound. It would constitute an undue burden to search all recited medicaments, as well as each medicament as related to the polymeric carrier, in terms of prior art and enablement.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

Claim Objections

The objection to Claim 11 for use of indefinite language as pertaining to particle size (e.g., "under 20 micrometers to under 10 micrometers") as set forth at p. 2 of the previous Office

Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of the explanation by Applicant (p. 4, Paper 7, 21 August 2002) and by the amendment which introduced a more definitive size limitation into the claim (Paper 7, 21 August 2002).

Claim Rejections

35 U.S.C. § 112, second paragraph.

The rejection of Claims 1-14 for being indefinite (e.g., "polymeric construct") as set forth at p. 2-3 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of the explanation by the Applicant (p. 4-5, Paper 7, 21 August 2002) that the term "polymeric construct" is adequately defined in the Specification.

The rejection of Claims 8, 11 and 14 for being indefinite (e.g., "suitable anti-solvent") as set forth at p. 3 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn in part* (see "Maintained Rejections" below) in view of the amendment which removed the word "suitable" from Claim 8 (p. 5-6, Paper 7, 21 August 2002).

The rejection of Claims 11-14 for being indefinite (e.g., "particles of such construct") as set forth at p. 4 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of the amendment which established an antecedent basis from Claim 8 to Claims 11-14 (p. 7, Paper 7, 21 August 2002).

The rejection of Claims 11-14 for being indefinite (e.g., "under 10 or under 20 micrometers") as set forth at p. 4 of the previous Office Action (Paper No. 4, 31 December,

2001) is *withdrawn* in view of the amendments of Claims 11-14 which specified a range of "under 10 micrometers" or "under 5 micrometers" (p. 7, Paper 7, 21 August 2002).

35 U.S.C. § 102(b)

The rejection of Claims 1, 2 and 6 for being anticipated by Goosen, et al (U.S. Patent 4,689,293), as set forth at p. 4 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric constituent (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that the Goosen, et al Patent teaches a method of microencapsulating *living cells* (p. 7-9, Paper 7, 21 August 2002).

35 U.S.C. § 103(a)

The rejection of Claims 3-5 for being anticipated by Goosen, et al (U.S. Patent 4,689,293) in view of Mathiowitz, et al (J. Appl. Polymer Sci, 1988, 35: 755-774), as set forth at p. 6-7 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric constituent (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that the Goosen, et al Patent teaches a membrane that remains semipermeable and effective for three to six months, but that is not necessarily biocompatible (p. 7-9, Paper 7, 21 August 2002). Nor would it be an obvious next step to make the Goosen, et al, membrane composition fast-dissolving or biocompatible.

The rejection of Claim 7 for being anticipated by Goosen, et al (U.S. Patent 4,689,293) in view of Mathiowitz, et al (Mathiowitz, et al, 1987, J. Controlled Release, 5: 13-22), as set forth at p. 7-8 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric constituent (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that the Goosen, et al Patent teaches a membrane that remains semipermeable and effective for three to six months, but that is not necessarily biocompatible (p. 11, Paper 7, 21 August 2002). Nor would it be an obvious step to make the Goosen, et al, membrane composition fast-dissolving or biocompatible, since that invention is designed to neither dissolve nor be biocompatible. Furthermore, as discussed by the Applicant (p. 11-12, Paper 7, 21 August 2002), Mathiowitz, et al, teaches methods of hot-melt microencapsulation, not -0.5 to 28°C, as taught in the instant Specification.

The rejection of Claim 8 for being anticipated by Goosen, et al (U.S. Patent 4,689,293) in view of Mathiowitz, et al (J. Appl. Polymer Sci, 1988, 35: 755-774), as set forth at p. 7-8 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric constituent (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that the Goosen, et al Patent teaches a membrane that remains semipermeable and effective for three to six months, but that is not necessarily biocompatible (p. 11, Paper 7, 21 August 2002). Nor would it be an obvious step to make the Goosen, et al, membrane composition fast-dissolving or biocompatible, since that invention is designed to neither dissolve nor be biocompatible (p. 12-13, Paper 7, 21 August

2002). Furthermore, the methods of drying the polymer, as stated in Claim 8, is not disclosed in either Goosen, et al or Mathiowitz, et al.

The rejection of Claim 9 for being anticipated by Goosen, et al (U.S. Patent 4,689,293) in view of Mathiowitz, et al (J. Appl. Polymer Sci, 1988, 35: 755-774), as set forth at p. 9-11 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric constituent (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that the Goosen, et al Patent teaches a membrane that remains semipermeable and effective for three to six months, but that is not necessarily biocompatible (p. 11, Paper 7, 21 August 2002). Nor would it be an obvious step to make the Goosen, et al, membrane composition fast-dissolving or biocompatible, since *that* invention is designed to neither dissolve nor be biocompatible (p. 13-14, Paper 7, 21 August 2002). Furthermore, the methods of drying the polymer, as stated in Claim 9, namely the use of a precipitating salt solution, is not disclosed in either Goosen, et al or Mathiowitz, et al.

The rejection of Claim 10 for being anticipated by Goosen, et al (U.S. Patent 4,689,293) in view of Mathiowitz, et al (Mathiowitz, et al, 1992, J. Appl. Polymer Sci, 45: 125-134), as set forth at p. 11-12 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric construct (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that both references teach different polymer systems and utilize different delivery mechanisms (p. 14, Paper 7, 21 August 2002). Nor would it be an obvious step to make the Goosen, et al, membrane composition fast-

dissolving or biocompatible, since the Goosen, et al invention is designed to neither dissolve nor be biocompatible (p. 14, Paper 7, 21 August 2002).

The rejection of Claims 11 and 12 for being anticipated by Goosen, et al (U.S. Patent 4,689,293) in view of Steiner, et al (U.S. Patent 6,071,497), as set forth at p. 12-13 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric construct (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that it would not be an obvious step to make the Goosen, et al, membrane composition fast-dissolving or biocompatible, since the Goosen, et al invention is designed to neither dissolve nor be biocompatible (p. 14, Paper 7, 21 August 2002). Furthermore, the Steiner, et al Patent teaches an ordered high-molecular weight polymer (e.g., a crystal) using different polymeric constituents (e.g., diketopiperazine) and utilizing different delivery mechanisms (p. 14-16, Paper 7, 21 August 2002), and teaches crystalline polymers with polylysine coatings.

The rejection of Claims 13 and 14 for being anticipated by Steiner, et al (U.S. Patent 6,071,497), in view of Edwards, et al (U.S. Patent 5,874,064) as set forth at p. 13-14 of the previous Office Action (Paper No. 4, 31 December, 2001) is *withdrawn* in view of Applicant's election of a single polymeric construct (e.g., "alginic acid") as well as a single medicament (e.g., "insulin") and by the Applicant's explanation that the polymer disclosed in Edwards, et al is comprised of amino acids, not carbohydrates, and that the particles are designed to be biodegradable (p. 17, Paper 7, 21 August 2002). Furthermore, the Steiner, et al Patent teaches an

ordered high-molecular weight polymer (e.g., a crystal), different polymeric constituents and utilizing different delivery mechanisms (p. 14-16, Paper 7, 21 August 2002).

Maintained Objections and/or Rejections

35 U.S.C. § 112, second paragraph.

The rejection of Claims 8, 9, 11, 12 and 14 for being indefinite (e.g., “anti-solvent”) as set forth at p. 3 of the previous Office Action (Paper No. 4, 31 December, 2001) is *maintained*. Although Applicants argue that “*anti-solvent* is well known and understood in the art” and that it is a “universal technical term” and the “exact opposite of the term ‘solvent’”, the Examiner could find no mention of the term anywhere in the instant Specification nor in the literature. (p. 5-6, Paper 7, 21 August 2002).

The rejection of Claims 8 and 9 for being indefinite (e.g., “a critical pressure and temperature”), as set forth at p. 3 of the previous Office Action (Paper No. 4, 31 December, 2001) is *maintained*. Applicants argue (p. 5-6, Paper 7, 21 August 2002) that the choice of conditions specified in the claims would depend, for example, on the nature of the medicament, and the choice of fluids and vehicles, as well as other practical criteria, and would be obvious to one of skill in the art. The examiner agrees that the choice of conditions specified in the claims would depend on the medicament, polymer constituents, and solvents, as well as pressures and temperatures. However, it is important to emphasize that the Applicant must specify the details and exact conditions needed to practice the elected invention. The steps which go into each

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elected invention must be clearly and positively specified. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). Although the claimed methods and products utilize routine techniques for making aerosols, the results of the methods are unpredictable and complex when considered with each combination of products.

New Objections and/or Rejections

Claim Objections

Claims 2, 4 and 5 are objected to for reciting non-elected inventions.

Claim Rejections

Non-Statutory Double-Patenting.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,475,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredients cited in each patent are identical; therefore, what is obvious in the Patent versus the instant Application is the mode of delivery of the medicament. Evidence for this is revealed in the data of Figure 1 of the 6,475,468 Patent which is identical to the data put forth in Figure 1 of the instant Application, showing the same mode of delivery in the Patent versus the instant Application.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

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Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sandra Wegert

11/13/02

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